## **COMMISSION IMPLEMENTING REGULATION (EU) 2017/54**

### of 14 December 2016

concerning the authorisation of 2-methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2-methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylvaleric acid, 2-methylbutyric acid, 2-methylbutyric acid, 2-methylheptanoic acid, 4-methylnonanoic acid, 4-methyloctanoic acid, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate and 2-methylbutyl butyrate as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (1), and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the reevaluation of additives authorised pursuant to Council Directive 70/524/EEC (²).
- 2-Methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2-methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylbutyric acid, 2-methylbutyric acid, 2-methylbutyric acid, 2-methylbutyric acid, 2-methylbutyrate, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate, isopentyl 2-methylbutyrate, 2-methylbutyl isovalerate and 2-methylbutyl butyrate, herereinafter referred to as 'the substances concerned' were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those additives to be classified in the additive category 'sensory additives'. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 October 2012 (3) that, under the proposed conditions of use in feed, the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority further concluded that those substances are flavouring agents authorised in food for which the efficacy is demonstrated as the functions of the additive applied for feed use and described for food use are similar.
- (5) The Authority concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the Method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> EFSA Journal 2012;10(10):2927.

- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation. Maximum recommended contents should be set up for those substances. Those substances may be used within a compound feed subsequently administered via water.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

## Article 1

#### Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

## Article 2

# Transitional measures

- 1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
- 2. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
- 3. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

# Article 3

#### **Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2016.

For the Commission The President Jean-Claude JUNCKER

17.1.2017

Official Journal of the European Union

L 13/83

Identifica- tion	Name of the		Composition, chemical	Species or		Minimum content	Maximum content		End of period
number of the additive	holder of authorisation	Additive	formula, description, analytical method	category of animal	Maximum age	complete feed	ubstance/kg of lingstuff with ntent of 12 %	Other provisions	of authoris- ation
(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)

# Category: Sensory additives. Functional group: Flavouring compounds

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2b02001		2-Methyl-propan-1-ol	Additive composition  2-Methylpropan-1-ol  Characterisation of the active substance  2-Methylpropan-1-ol  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>4</sub> H <sub>10</sub> O  CAS number 78-83-1  FLAVIS 02.001  Method of analysis (¹)  For the determination of 2-Methylpropan-1-ol in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species		<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
						6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02003 —	Isopentanol	Additive composition  Isopentanol  Characterisation of the active substance  Isopentanol  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>5</sub> H <sub>12</sub> O  CAS number 123-51-3  FLAVIS 02.003  Method of analysis (¹)  For the determination of Isopentanol in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7	")	(8)	(9)
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2b02026		3,7-Di- methyloc- tan-1-ol	Additive composition  3,7-Dimethyloctan-1-ol  Characterisation of the active substance  3,7-Dimethyloctan-1-ol  Produced by chemical synthesis  Purity: min. 90 %  Chemical formula: C <sub>10</sub> H <sub>22</sub> O  CAS number 106-21-8  FLAVIS 02.026  Method of analysis (¹)  For the identification of 3,7-Dimethyloctan-1-ol in the feed additive and flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be:         <ul> <li>for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> </ul> </li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	. 13/86
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		86 EN 8
2b02082		2-Ethyl- hexan-1-ol	Additive composition  2-Ethylhexan-1-ol  Characterisation of the active substance  2-Ethylhexan-1-ol  Produced by chemical synthesis  Purity: min. 97 %  Chemical formula: C <sub>8</sub> H <sub>18</sub> O  CAS number 104-76-7  FLAVIS 02.082  Method of analysis (¹)  For the determination of 2-Ethylhexan-1-ol in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)	
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		
2b05004		2-Methyl-propanal	Additive composition  2-Methylpropanal  Characterisation of the active substance  2-Methylpropanal  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>4</sub> H <sub>8</sub> O  CAS number 78-84-2  FLAVIS 05.004  Method of analysis (¹)  For the determination of 2-Methylpropanal in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Cinema John mar or the European Cinem

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	. 13/88
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.		88 EN
2b05006		3-Methylbu- tanal	Additive composition  3-Methylbutanal  Characterisation of the active substance  3-Methylbutanal  Produced by chemical synthesis  Purity: min. 95 %  Chemical formula: C <sub>5</sub> H <sub>10</sub> O  CAS number 590-86-3  FLAVIS 05.006  Method of analysis (¹)  For the determination of 3-Methylbutanal in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(	7)	(8)	(9)
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2b05049		2-Methylbutyraldehyde	Additive composition  2-Methylbutyraldehyde  Characterisation of the active substance  2-Methylbutyraldehyde  Produced by chemical synthesis  Purity: min. 97 %  Chemical formula: C <sub>5</sub> H <sub>10</sub> O  CAS number 96-17-3  FLAVIS 05.049  Method of analysis (¹)  For the determination of 2-Methylbutyraldehyde in the feed additive and in feed flavouring premixtures.  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	. 13/90
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.		90 EN
2b08008		3-Methylbutyric acid	Additive composition  3-Methylbutyric acid  Characterisation of the active substance  3-Methylbutyric acid  Produced by chemical synthesis  Purity: min. 99 %  Chemical formula: C <sub>5</sub> H <sub>10</sub> O <sub>2</sub> CAS number 503-74-2  FLAVIS 08.008  Method of analysis (¹)  For the determination of 3-Methylbutyric acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

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2b08031		2-Methylva- leric acid	Additive composition  2-Methylvaleric acid  Characterisation of the active substance  2-Methylvaleric acid  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>6</sub> H <sub>12</sub> O <sub>2</sub> CAS number 97-61-0  FLAVIS 08.031  Method of analysis (¹)  For the determination of 2-Methylvaleric acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7	)	(8)	(9)	. 13/92
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.		92 EN
2b08045		2-Ethylbuty- ric acid	Additive composition  2-Ethylbutyric acid  Characterisation of the active substance  2-Ethylbutyric acid  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>6</sub> H <sub>12</sub> O <sub>2</sub> CAS number 88-09-5  FLAVIS 08.045  Method of analysis (¹)  For the determination of 2-Ethylbutyric acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

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b08046 —	2-Methylbutyric acid	Additive composition  2-Methylbutyric acid  Characterisation of the active substance  2-Methylbutyric acid  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>5</sub> H <sub>10</sub> O <sub>2</sub> CAS number 116-53-0  FLAVIS 08.046  Method of analysis (¹)  For the determination of 2-Methylbutyric acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)	L 13/94
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		94 EN
2b08047		2-Methyl-heptanoic acid	Additive composition  2-Methylheptanoic acid  Characterisation of the active substance  2-Methylheptanoic acid  Produced by chemical synthesis  Purity: min. 97 %  Chemical formula: C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> CAS number 1188-02-9  FLAVIS 08.047  Method of analysis (¹)  For the determination of 2-Methylheptanoic acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

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2b08062		4-Methylnonanoic acid	Additive composition  4-Methylnonanoic acid  Characterisation of the active substance  4-Methylnonanoic acid  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>10</sub> H <sub>20</sub> O <sub>2</sub> CAS number 45019-28-1  FLAVIS 08.062  Method of analysis (¹)  For the identification of 4-Methylnonanoic acid in the feed additive and flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be:         <ul> <li>for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> </ul> </li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2)	(3)	(4)	(5)	(6)	(7	)	(8)	(9)	13
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		13/96 EN
2b08063 —	4-Methyloctanoic acid	Additive composition  4-Methyloctanoic acid  Characterisation of the active substance  4-Methyloctanoic acid  Produced by chemical synthesis  Purity: min. 97 %  Chemical formula: C <sub>9</sub> H <sub>18</sub> O <sub>2</sub> CAS number 54947-74-9  FLAVIS 08.063  Method of analysis (¹)  For the determination of 4-Methyloctanoic acid in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	")	(8)	(9)	
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.		
2b09005		Isobutyl acetate	Additive composition Isobutyl acetate  Characterisation of the active substance Isobutyl acetate  Produced by chemical synthesis  Purity: min. 95 %  Chemical formula: C <sub>6</sub> H <sub>12</sub> O <sub>2</sub> CAS number 110-19-0  FLAVIS 09.005  Method of analysis (¹)  For the determination of Isobutyl acetate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	CHEMI JOHNM OF THE PHY SPORT CHICK

(1) (2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	L 13/98
						6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.		98 EN
2b09043 —	Isobutyl butyrate	Additive composition Isobutyl butyrate  Characterisation of the active substance Isobutyl butyrate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> CAS number 539-90-2  FLAVIS 09.043  Method of analysis (¹)  For the determination of Isobutyl butyrate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
b09070		3-Methylbutyl hexanoate	Additive composition  3-Methylbutyl hexanoate  Characterisation of the active substance  3-Methylbutyl hexanoate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>11</sub> H <sub>22</sub> O <sub>2</sub> CAS number 2198-61-0  FLAVIS 09.070  Method of analysis (¹)  For the identification of 3-Methylbutyl hexanoate in the feed additive and flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be:         <ul> <li>for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> </ul> </li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09103		3-Methylbutyl dode- canoate	Additive composition  3-Methylbutyl dodecanoate  Characterisation of the active substance  3-Methylbutyl dodecanoate  Produced by chemical synthesis  Purity: min. 97 %  Chemical formula: C <sub>17</sub> H <sub>34</sub> O <sub>2</sub> CAS number 6309-51-9  FLAVIS 09.103  Method of analysis (¹)  For the identification of 3-Methylbutyl dodecanoate in the feed additive and flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be:         <ul> <li>for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> </ul> </li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2	()	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
b09120 —		-Methylbu- vl octano- te	Additive composition  3-Methylbutyl octanoate  Characterisation of the active substance  3-Methylbutyl octanoate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>13</sub> H <sub>26</sub> O <sub>2</sub> CAS number 2035-99-6  FLAVIS 09.120  Method of analysis (¹)  For the identification of 3-Methylbutyl octanoate in the feed additive and flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be:         <ul> <li>for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> </ul> </li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2)	(3)	(4)	(5)	(6)	(7)	1	(8)	(9)	. 13/
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		13/102 EN
b09136 —	3-Methylbutyl propionate	Additive composition  3-Methylbutyl propionate  Characterisation of the active substance  3-Methylbutyl propionate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> CAS number 105-68-0  FLAVIS 09.136  Method of analysis (¹)  For the determination of 3-Methylbutyl propionate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09162		3-Methylbutyl formate	Additive composition  3-Methylbutyl formate  Characterisation of the active substance  3-Methylbutyl formate  Produced by chemical synthesis  Purity: min. 92 %  Chemical formula: C <sub>6</sub> H <sub>12</sub> O <sub>2</sub> CAS number 110-45-2  FLAVIS 09.162  Method of analysis (¹)  For the determination of 3-Methylbutyl formate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	13/
						6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		13/104 EN
2b09211 —	Glyceryl tri- butyrate	Additive composition Glyceryl tributyrate Characterisation of the active substance Glyceryl tributyrate Produced by chemical synthesis Purity: min. 99 % Chemical formula: C <sub>15</sub> H <sub>26</sub> O <sub>6</sub> CAS number 60-01-5 FLAVIS 09.211 Method of analysis (¹) For the determination of Glyceryl tributyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	")	(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09417		Isobutyl isobutyrate	Additive composition Isobutyl isobutyrate  Characterisation of the active substance Isobutyl isobutyrate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>8</sub> H <sub>16</sub> O <sub>2</sub> CAS number 97-85-8  FLAVIS 09.417  Method of analysis (¹)  For the determination of Isobutyl isobutyrate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09419		Isopentyl isobutyrate	Additive composition Isopentyl isobutyrate Characterisation of the active substance Isopentyl isobutyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C <sub>9</sub> H <sub>18</sub> O <sub>2</sub> CAS number 2050-01-3 FLAVIS 09.419 Method of analysis (¹) For the determination of Isopentyl isobutyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

(1) (2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	17.1.
						6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		17.1.2017 EN
2b09472 —	Isobutyl isovalerate	Isobutyl isovalerate  Characterisation of the active substance  Isobutyl isovalerate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>9</sub> H <sub>18</sub> O <sub>2</sub> CAS number 589-59-3  FLAVIS 09.472  Method of analysis (¹)  For the determination of Isobutyl isovalerate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union L 13/107

(1)	(2)	(3)	(4)	(5)	(6)	(7	)	(8)	(9)	. 13/
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		13/108 EN
2b09530		Isopentyl 2-methylbuty-rate	Additive composition Isopentyl 2-methylbutyrate Characterisation of the active substance Isopentyl 2-methylbutyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C <sub>10</sub> H <sub>20</sub> O <sub>2</sub> CAS number 27625-35-0 FLAVIS 09.530 Method of analysis (¹) For the determination of Isopentyl 2-methylbutyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	_			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union 17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7	7)	(8)	(9)	17.1.
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment		7.1.2017 EN
2b09531		2-Methylbutyl isovalerate	Additive composition  2-Methylbutyl isovalerate  Characterisation of the active substance  2-Methylbutyl isovalerate  Produced by chemical synthesis  Purity: min. 98 %  Chemical formula: C <sub>10</sub> H <sub>20</sub> O <sub>2</sub> CAS number 2445-77-4  FLAVIS 09.531  Method of analysis (¹)  For the determination of 2-Methylbutyl isovalerate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027	Official Journal of the European Union L 13/109

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09659		2-Methylbutyl butyrate	Additive composition  2-Methylbutyl butyrate  Characterisation of the active substance  2-Methylbutyl butyrate  Produced by chemical synthesis  Purity: min. 95 %  Chemical formula: C <sub>9</sub> H <sub>18</sub> O <sub>2</sub> CAS number 51115-64-1  FLAVIS 09.659  Method of analysis (¹)  For the determination of 2-Methylbutyl butyrate in the feed additive and in feed flavouring premixtures:  Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</li> <li>The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %.</li> <li>On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.</li> <li>Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.</li> </ol>	6 February 2027

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17.1.2017

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports